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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,625	02/07/2000	WINOK DEBYSER	550-392	7510
23117	7590	11/18/2004		
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714				
			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,625	DEBYSER ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-57 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-50, 52-56 and 65-68 is/are rejected.
- 7) ☒ Claim(s) 51 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 48-57 and 65-68 are under consideration in this Office Action.
2. The rejection of claims 48-57 and 65-68 under 35 U.S.C. 112, first paragraph, as lacking enablement has been withdrawn in view of applicants' arguments.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 48-50, 52-56 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 07/19/2004 have been fully considered but they are not persuasive. Applicants' position is that the claimed invention is supported by an adequate written description, that the specification provides a functional and structural description of the claimed xylanase inhibitors, and that contrary to issues before the *Eli Lilly* court the claims recite a reference sequence and a percent identity. The Examiner respectfully disagrees with Applicants' position for reasons of record and for the reasons stated below.

The claims are genus claims that are directed toward (1) any xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1 a molecular weight of 40-43 kDa, and pI of greater than about 7.0; or (2) any xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein having a molecular weight of 40-43 kDa which resolves as two separate bands having molecular weights of about 30kDa and about 10kDa after reduction with beta-mercaptoethanol. The scope of the claim includes many proteins with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members is permitted.

The specification describes a xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequences of SEQ ID NO: 1 and SEQ ID NO: 2, a

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molecular weight of 40-43 kDa, and pI of greater than about 7.0.

The specification and sequence listing show that SEQ ID NO:1 is a sequence of 14 amino acids and SEQ ID NO: 2 is a sequence of 17 amino acids. It is known in the art that the average molecular mass of an amino acid residue in a protein is about 0.11 kDa (See Proteins: Structures and Molecular Properties, 2nd ed.(1993), Thomas E. Creighton, p. 4, Table 1.1). Thus, the described xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein having a molecular weight of 40-43 kDa is a protein that contains approximately 333-358 amino acid residues.

The specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately approximately 333-358 amino acid residues of the claimed protein xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. No significant amino acid sequence and structure which is common to all members of the claimed genus has been described. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Since the disclosure fails to describe the significant amino acid sequence and structure which is common to all members of the genus, and because the genus is highly variant, recitation of SEQ ID NO: 1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusion

5. No claim is allowed.

6. Claims 51 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

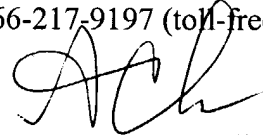
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday to Thursday and alternate Fridays between 9:00AM - 5:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



CHRISTIAN L FRONDA
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